

## **REMARKS/ARGUMENTS**

### **(1) Summary of Office Action**

In the Office Action (made final) dated February 13, 2007, the Examiner rejected claims 49 to 69 as being unpatentable under 35 U.S.C. §103(a) in light of the combination of European Patent Application No. 0 466 244 of Unilever NV with European Patent Application No. 0 955 061 of Medipharma and the teachings of Ibrahim and Nippon.

### **(2) Applicant's Submissions**

The applicant respectfully disagrees with the Examiner's finding of obviousness in respect of claims 49 to 69. In this regard, the applicant respectfully submits that the case for *prima facie* obviousness has not been established since there is no teaching, suggestion or motivation to combine the cited references in the manner suggested by the Examiner.

As a preliminary observation, the applicant notes that the Examiner uses the Unilever reference as the primary reference in her proposed combination. The Examiner identifies that the Unilever composition has improved antibacterial properties and comprises a mixture of at least one representative of each group (a) a cell wall lysing substance (b) an antimicrobial compound and an adjuvant such as an organic acid or sequestering agent. Moreover, the Examiner correctly acknowledges that: "Unilever differs from the claims in that their composition is not disclosed as containing egg powder or albumen and further to suppress the growth of enteric pathogens, specifically *Clostridium* sp., *E. coli*. and *Salmonella* sp." (see page 4, second paragraph). From the foregoing it is clear that the Examiner recognizes that Unilever does not teach an antimicrobial composition for suppressing the growth of enteric pathogens in the gut of a livestock - which feature the applicant considers to be a novel and unobvious feature of the claimed antimicrobial composition of claim 49.

The Examiner employs the Medipharma reference for its teaching of the use of freeze-dried eggs in an oral product for the prevention and therapy of porcine gastroenteric infections (i.e. the rotavirus, coronaviruses and enteropathogenic and enterotoxigenic bacterial strains of *Clostridium* sp., *E. Coli* and *Salmonella* Sp.) The

Examiner further relies on the teachings of Ibrahim and Nippon as to why one would use egg or albumen in an antimicrobial composition.

As understood by the applicant, the Examiner seems to be drawing the motivation to combine the references in the manner suggested from the teachings of Medipharm, Ibrahim and Nippon. However, it is the applicant's respectful view that these references cannot serve to provide the requisite motivation to include egg or albumen in just any antimicrobial composition. While these references may provide some justification or expectation of success for adding egg or albumen to a composition where the antimicrobial activity of the composition occurs *in vivo* (i.e. in the gut of livestock) and targets the growth of enteric pathogens, the teachings of these references cannot be distorted to provide motivation for the addition of egg or albumen to an antimicrobial composition which targets the suppression of bacterial growth *ex vivo* (i.e. on inanimate objects).

The Examiner has readily admitted that Unilever does not teach an antimicrobial composition for suppressing the growth of enteric pathogens in the gut of a livestock. Moreover, it is clear from the reference that the antimicrobial activity of Unilever's composition occurs *ex vivo*. Unilever's composition has been shown to be effective in suppressing the growth of *Listeria* bacteria in various products, including animal feedstuffs, cosmetic products or pharmaceutical products. Unilever further teaches treating the equipment used for handling or processing these products by contacting them with the antimicrobial composition (see page 5, lines 47 to 50). Unilever recommends that the lysing substances, antibacterials or adjuvants should be edible when used for foods, although for other applications non-edible ingredients may also be used. Unilever attempts to address the problem of bacterial contamination of products. It seeks to eradicate the spread of bacteria on equipment or feed.

The applicant has found nothing in this reference that would suggest that Unilever's antimicrobial composition could be used for veterinary purposes - more specifically, to suppress the growth of enteric pathogens in the gut of livestock - either alone or in combination with other ingredients. Neither Medipharm, nor Ibrahim or Nippon suggests using the composition of Unilever (i.e. a composition having antimicrobial activity occurring *ex vivo* and adapted for suppressing the growth of

*Listeria* bacteria in products) and adding egg or albumen to suppress enteric pathogens in the gut of livestock (i.e. *in vivo*).

Moreover, there are additional reasons why a person skilled in the art would not be brought to combine the references as suggested by the Examiner. Absent a teaching in one of the cited references, a person skilled in the art would not automatically assume that the antimicrobial composition of Unilever which is effective in suppressing *Listeria* bacteria on a product, would also be effective (when combined with egg or albumen) to suppress enteric pathogens in the gut of livestock. The bacteria being suppressed by the Unilever composition is *Listeria* bacteria whereas the composition of claim 49 is for suppressing the growth of enteric pathogens (i.e. *Clostridium perfringens*) in the gut of livestock. These bacteria are different and thrive in different environmental conditions (i.e. pH, temperature, water content or activity, co-existence with other bacteria etc.). Because of these differences, one skilled in the art could not readily conclude (based on the bacterial suppression activity of the Unilever composition applied to a product) that the composition of Unilever (as proposed to be modified by the Examiner) would have any effectiveness whatsoever against enteric pathogens in the gut of livestock.

In summary, the applicant respectfully submits that the Examiner has rejected claims that narrowly define a set of active ingredients, which generate an unexpected and desirable result in the gut of an animal. The primary reference (Unilever) applied by the Examiner teaches an alternate combination of materials that are described as suppressing spoilage in a foodstuff. No teaching is provided by the primary reference on any effect of these materials in the gut of an animal. Secondary references show pharmaceutical preparations that differ from the claimed compositions but that do treat a separate and distinct disease state in the animal. There are no teachings or suggestions in any of the references which would encourage one of ordinary skill to substitute ingredients or to use an *ex vivo* foodstuff treatment as an *in vivo* pharmaceutical composition.

Claims 50 - 67 ultimately depend from claim 49 and are directed toward various features of the claimed orally administrable antimicrobial composition. Insofar as claim

49 is presently allowable over the cited prior art, the applicant respectfully submits that claims 50 - 67 are also allowable.

In respect of claims 68 and 69, the applicant respectfully submits that the claims 68 and 69 are patentable over the cited prior art for the reasons set out above, as adapted to reflect that the claimed composition of claims 68 and 69 is for treating gastrointestinal infections in livestock.

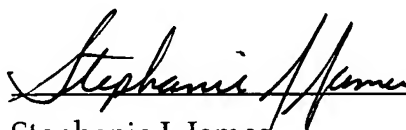
(3) **Conclusion**

The present amendment imports no new subject matter into the application.

Consideration of the above-identified application is respectfully requested. If after reviewing this amendment, the Examiner believes that a telephone or personal interview would facilitate the resolution of any remaining matters, the undersigned attorney may be contacted at the number set forth herein below.

Respectfully submitted,  
NEOVA TECHNOLOGIES, INC.  
By its attorneys:

Date: 0/13/07



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